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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

1547/00268

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/509869

INTERNATIONAL APPLICATION NO. PCT/SE98/01982

INTERNATIONAL FILING DATE 3 November 1998

PRIORITY DATE CLAIMED 11 November 1997

TITLE OF INVENTION

ARRANGEMENT FOR OBTAINING RELIABLE ANCHORING OF A THREADED IMPLANT IN BONE

APPLICANT (S) FOR DO/EO/US

Lennart Carlsson, Fredrik Engman, Roger Fromell and Lars Jörnéus

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- 1. It is a FIRST submission of items concerning a filing under 35 U S.C. § 371
- 2. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. § 371.
- 3. A This express request to begin national examination procedures (35 U.S.C. § 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. § 371(b) and PCT Articles 22 and 39(1).
- 4. 🖾 A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
- 5. ☑ A copy of the International Application as published (35 U.S.C. § 371(c)(2)) WO 99/23971
 - is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. \Box has been transmitted by the International Bureau.
 - c.

 is not required, as the application was filed in the United States Receiving Office (RO/US).
- 6. ☐ A translation of the International Application into English (35 U.S.C. § 371(c)(2)).
- 7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. § 371(c)(3))
 - a. \square are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. D have been transmitted by the International Bureau.
 - c. \square have not been made; however, the time limit for making such amendments has NOT expired.
 - d.

 have not been made and will not be made.
- B. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. § 371(c)(3).
- 9. \square An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
- 10. ☐ A translation of the Annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

- 11.□ An Information Disclosure Statement under 37 CFR 1.97 and 1.98. (w/ references & Form PTO-1449)
- 12.□ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
- 13.☑ A FIRST preliminary amendment.
 - ☐ A SECOND or SUBSEQUENT preliminary amendment.
- 14. ☐ A substitute specification.
- 15. ☐ A change of power of attorney and/or address letter
- 16. ☑ Other items or information:

Form PCT/IB/308 - Notice Informing The Applicant Of The Communication Of The International Application To The Designated Offices, Form PCT/RO/101 - PCT Request, Form PCT/IB/306 - Notification Of The Recording Of A Change, Form PCT/IPEA/409 - International Preliminary Examination Report w/amended claims & 4 sheets formal drawings

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u.s. application no. (if k	CATION NO. (If known, see 37 CFR 1 5) INTERNATIONAL APPLICATION NO. PCT/SE98/01982		ATTORNEY'S DOCKET NUMBER 1547/00268						
The following fees ar	e submitted:			CALCULATIONS	PTO USE ONLY				
Basic National Fee (37 C Search Report has been p International preliminary	repared by the EPO or JI		\$840.00 \$670.00						
No international preliming search fee paid to USPTC			,						
Neither international preli CFR 1.445(a)(2)) paid to	•	(37 CFR 1.482) nor inter-	national search fee (37 \$970.00						
International preliminary provisions of PCT Article		JSPTO (37 CFR 1.482) a	and all claims satisfied \$96.00		,				
	ENTER	\$970.00							
Surcharge of \$130.00 for fur claimed priority date (37 CF	-	\$130.00							
Claims	Number Filed	Number Extra	Rate						
Total Claims	12 - 20 =	0	X \$18.00	\$0.00					
Independent Claims	1 - 3 =	0	X \$78.00	\$0.00					
Multiple dependent clair	Multiple dependent claim(s)(if applicable) + \$270.00								
		\$1,100.00							
Reduction by 1/2 for filing b (Note 37 CFR 1.9, 1.27, 1.2		\$0.00							
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Processing fee of \$130.00 fo claimed priority date (37 CF)		slation later than □ 20 □ 30	months from the earliest	\$					
1155		TOTAL	NATIONAL FEE =	\$1,100.00					
Fee for recording the enclose appropriate cover sheet (37.0)	- '	\$0.00							
TOTAL FEES ENCLOSED = \$1,100.00									
a. A check in the amount of \$1,100.00 to cover the above fees is enclosed.									
b. Please charge my Deposit Account No 22-0185 in the amount of \$0 to cover the above fees. A duplicate copy of this sheet is enclosed.									
c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No 22-0185. A duplicate copy of this sheet is enclosed.									
NOTE: Where an appropr		FR 1.494 or 1.495 has not l	been met, a petition to rev	ive (37 CFR 1.137(a) or (b) must be filed and				
SEND ALL CORRESPOND Pollock, Vande Sande & An 1990 M Street, N.W. Suite 800	mernick, R.L.L.P.	SIGINITORES		opeda 04-	03-2000				
Washington, DC 20036-3425	ashington, DC 20036-3425 Elzbieta Chlopecka, Reg. No. 32,767 NAME								

430 Rec'd PCT/PTO 0 3 APR 2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Lennart Carlsson et al.

Serial No. Unknown

U.S. Patent Application of

PCT/SE98/01982

Filed: April 3, 2000

For:

ARRANGEMENT

FOR

OBTAINING RELIABLE ANCHORING

OF A THREADED IMPLANT IN BONE

Atty Docket: 1547/00268

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Prior to examination and filing fee calculation, please amend the above-identified application as follows:

IN THE CLAIMS (Amended sheets):

Please amend the following claims:

Claim 3, line 1, delete "or 2";

Claim 7, lines 1-2, delete "or any of claims 5-6";

Claim 8, lines 1-2, delete "or any of claims 5-7";

Claim 9, lines 1-2, delete "or any of claims 5-8";

Claim 12, line 1, delete "or 11".

REMARKS

Claims 1-12 are pending in this application. By the foregoing amendment, claims 3, 7-9 and 12 have been amended to eliminate multiple dependencies and thus reduce the filing fee.

Date: 04-03-2000

These amendments to the claims are not believed to introduce any new matter, and entry of this amendment is respectfully requested.

Favorable consideration of this case is respectfully requested.

Respectfully submitted,

Elshieta Culopecka Elsbieta Chlopecka, Reg. No. 32,767

Pollock, Vande Sande & Amernick, R.L.L.P.

1990 M Street, N.W.

Washington, D. C. 20036-3425

Telephone: 202-331-7111

WO 99/23971

TITLE

ARRANGEMENT FOR OBTAINING RELIABLE ANCHORING OF A THREADED IMPLANT IN BONE

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TECHNICAL FIELD:

The present invention relates to an arrangement permitting anchoring of a threaded implant in bone, for example dentine, in the human body by means of a screwing/tightening instrument. At its upper part, the implant has an anchoring hole for a unit, preferably in the form of a screw, intended to secure an element that can be attached to the implant and can in this case consist of a fixture holder, fixture, spacer, etc. The centre axis of the anchoring hole is also inclined in relation to the longitudinal axis of the implant.

The invention also relates to the use of an element, for example in the form of a fixture holder, fixture, spacer, etc., which can be attached to a threaded implant, where the implant is screwed into a bone, for example the dentine, by means of an instrument and where the implant has an anchoring hole for the securing unit, preferably in the form of a screw, for the element in question.

PRIOR ART

The invention is further concerned with the screwing functions of implants of the type described, inter alia, in Swedish Patent 9203563-3 and PCT application WO 96/18355. A characteristic of this type of implant is the presence of an inclined threaded hole which can be arranged in a fixture for the implant or in the actual implant itself. The centre axis of the hole is inclined in relation to the axis of rotation of the implant. When anchoring further fixtures, spacers, etc. in the implant, an anchoring screw is used which can be

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screwed tightly into the internal thread of the anchoring hole.

The said PCT document mentions the possibility of using screwing instruments which are connected to the upper parts of the implant for the purpose of screwing the implant tightly into the bone in question.

DESCRIPTION OF THE INVENTION

TECHNICAL PROBLEM

A reliable and as far as possible simplified tightening function needs to be found. The invention is intended to solve this problem, among others.

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The said PCT document proposes an instrument which uses the anchoring screw for securing a fixture to the implant. The instrument is provided with an inclined recess which coincides with or constitutes a continuation of the anchoring hole. The anchoring screw is in this case removed first, and the instrument is applied in such a way that the recess of the instrument is arranged concentrically in relation to the recess in the implant, after which they can be screwed tight by means of the said anchoring screw. When the implant has been tightened, the anchoring screw is loosened and removed, after which the instrument can also be removed. This procedure is a lengthy one. The inclined recess in the instrument is deep and problems can occur during screwing, unscrewing, etc., of the anchoring screw in question. The present invention is intended to solve this problem too.

It may be desirable not to have to act on the anchoring screw during the tightening or screwing-in of the implant into the bone. The invention solves this problem too.

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SOLUTION

The feature which can principally be regarded characterizing arrangement according an to the invention is, inter alia, that the element (fixture holder, fixture, etc.) that can be attached by means of the said unit (screw) is provided with means of cooperation with the instrument, and that the element and its means of cooperation are arranged to permit application of the instrument in a way which ensures that the axis of rotation of the instrument essentially coincides with the continuation of the axis of rotation of the implant.

An arrangement according to the invention can principally be regarded as being characterized by the fact that the tightening function exerted by means of the instrument is separate from the securing function exerted by means of the unit (screw) by virtue of the fact that the element (fixture holder, fixture, spacer, etc.) has a first portion via which the element is anchored by the anchoring unit in the implant, and a second portion which is separate from the first portion and which has cooperating means for the instrument.

Embodiments of the arrangement are specified in the attached subclaims.

The use according to the invention can principally be regarded as being characterized by the fact that the element (fixture holder, fixture, spacer, etc.) is used in the tightening operation with the instrument by virtue of the fact that the element has means cooperating with the instrument, to which means the instrument is applied with its axis of rotation essentially coinciding with the continuation of the axis of rotation of the implant.

Further developments of the said use are specified in the attached subclaims.

ADVANTAGES

By means of what has been proposed above, a considerably simplified and less expensive tightening function is obtained for implants in dentine. The handling of small tightening screws can be avoided, and simple application to the implant for turning it or

- screwing it in can be effected. The locking function for the instrument can be made extremely simple by the fact that a conventional locking screw can be used in a manner known per se. The implant with associated element, i.e. fixture holder, fixture, spacer, etc.,
- 15 can be supplied as one unit to which the tightening instrument can be applied in an extremely simple and effective manner.

DESCRIPTION OF THE FIGURES

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A presently proposed embodiment of an arrangement and use having the significant characteristics of the invention will be described below with reference to the attached drawings, in which:

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Figure 1 shows, in a vertical view and partial cross section, an implant which has been partially screwed into dentine by means of an instrument (screwing instrument),

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- Figure 2 shows, in a vertical section, and enlarged in relation to Figure 1, the implant together with a fixture holder screwed into the latter,
- Figure 3 is a plan view of means which are arranged on the upper part of the fixture holder and can cooperate with the instrument,

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Figure 4 shows, in vertical section along the line A-A, the design of the fixture holder,

Figure 5 shows, obliquely from above, the design of a nut-shaped part on the implant, and

Figure 6 shows the upper parts of the implant from the side, with the associated nut-shaped part according to Figure 5.

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DETAILED EMBODIMENT

In Figures 1 and 2, an implant is indicated by 1. The implant is intended to be screwed into dentine 2, and it can be screwed into a pre-drilled hole 3. implant can be of the self-tapping type and is in this case provided with an external thread la. Attached to the upper parts of the implant there is an element 4, for example in the form of a fixture holder. This can be attached or applied by means of a screw 5 or other anchoring unit. An instrument, for example in the form of a screwing instrument 6 with shaft-like part 6a and handle part 6b, can be attached/applied to the upper parts or portion 4a of the element. The instrument is provided with a locking arrangement, for example in the form of a locking screw 7. The fixture holder 4 is provided with a second portion 4b which is separate from the first portion 4a.

The axis of rotation (longitudinal axis) of the implant is indicated by 1b, and the longitudinal axis or axis of rotation of the screw 5 is shown by 5a. The implant has an inclined, threaded recess 1c, in which the screw 5 can be screwed or the unit can be anchored. The centre axis of the hole coincides with the centre axis 5a of the screw. The centre axis of the hole slopes at an angle, for example an angle of about 45°, in relation to the longitudinal axis 1b of the implant. The said second portion 4b has a recess 4c which is

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concentric in relation to the recess lc when the holder is in its secured position on the implant. The head 5b of the screw 5 is partially engaged in the recess 4c when the holder is in its secured position in the implant.

The upper portion 4a of the holder 4 is provided with a key grip 4d. The holder 4 is additionally provided with a central recess 4e (can be threaded) which opens at the top, and a transverse recess 4f in the bottom part of the recess. The centre line 4g of the holder coincides essentially with the axis of rotation 1b of the implant. The centre line of the hole 4e coincides with the centre line 4g of the holder 4. A shoulder portion of the holder is shown by 4h. The upper part of the implant is shown by 1d.

Figure 3 shows a four-sided key grip for the instrument 6 which is provided with a corresponding internal four-wall recess 6c (Figure 1). The key grip can have another number of sides, and the recess 6c likewise can have another number of corresponding walls. The part bearing the shoulder portion 4h can have a diameter of about 6 mm, and the external dimension d of the key grip can be about 3.9 mm.

Figure 4 shows that the recess 4c passes into subsidiary recesses 4c' and 4c'', of which 4c' is threaded. The diameter of the recess 4c' is less than the diameter of the recess 4c so as to form a shoulder 4c'' with which an underside 5b' (see Figure 2) of the screw 5 cooperates or on which it bears when the screw is in the screwed-in position. The holder 4 has an inclined surface 4i which slopes at an angle α of about 45° in relation to the axis 4g.

Figures 5 and 6 show the outer shape of the implant which in this case comprises a hexagonal nut 1c to which the holder 4 can be fixed in rotation by means of

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the recess 4c' which is designed with an internal hexagon shape corresponding to the outer shape of 1c. Other numbers of edges can be used.

- 5 The method can in this case be that the holder is first anchored to the implant by the recess 4c'' brought over the nut shape 1c and the member 5 thereafter being applied and made fast (screwed). The instrument can thereafter be engaged on the four-edged 10 shape 4d via its corresponding four-edged recess 6d, after which the locking member 7 is activated (the locking nut is tightened). When the implant is screwed fully into the dentine 2, the locking member 7 is deactivated and the instrument 6 is removed from the 15 holder 4, which in this way can be left in place, i.e. the unit or the screw 5 does not need to be removed, screwed tight and once again removed in order finally to be screwed back again into the respective recess.
- 20 The new arrangement is thus characterized by the fact that the tightening function exerted by means of the instrument is separate from the securing function which is exerted by the said unit or screw 5. The said functions are attributable to different parts of the 25 holder, spacer, fixture, etc., which parts are thus separate or distinct. One element, for example in the form of a holder according to the above, can in this case be used in the screwing function by means of the instrument, the instrument being applied in such a way 30 that the instrument 6d coincides with the longitudinal axis 1b of the implant. Reference is made to Figure 1 where it can be seen that the direction longitudinal axis 6d of the instrument coincides with the continuations of the longitudinal axes 1b and 4g, 35 respectively, of the implant and of the fixture holder.

Figure 6 shows an inclined surface of the implant indicated by le. This surface slopes in relation to the longitudinal axis 1b of the implant by an angle α .

which essentially corresponds to the angle α in Figure 4. The arrangement is also such that when the surfaces 4i and le bear against each other, the longitudinal axes 4g and 1b essentially coincide, which is also true of the longitudinal axis 6d of the instrument since the key grip 4d is arranged concentrically around the longitudinal axis 4g of the holder.

The invention is not limited to the embodiment shown above by way of example, but can be modified within the scope of the attached patent claims and the inventive concept.

bone.



PCT/SE98/01982

PATENT CLAIMS

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1. Threaded implant (3) for obtaining reliable anchoring in bone substance (1), preferably in the jaw-bone, in the human body, the bone substance being provided with a hole (2) in whose side wall 10 it is possible to establish an internal threading (1a) which can cooperate with an external threading (3d, 3d') on the implant for reliable anchoring and healing-in of the implant in the bone substance, characterized in that the threading is arranged, particularly in the case of 15 soft bone substance, to force the bone substance out in essentially radial directions (R) as a function of the extent to which the implant is screwed into the hole, that the implant threading has a slight conicity which extends along most or part of 20 the length (L) of the implant and which cooperates with a circular cylindrical hole (2) in the bone (1) to effect greater forcing out of the bone substance at the outer parts (2c) of the hole than at 25 the inner parts (2d) of the hole, the degree of forcing out being adapted in relation to the softness of the bone substance in order to achieve the reliable anchoring, and that said conical threading comprises two or more thread spirals (thread en-30 despite shortening the tries) which, time screwing the implant into the hole, provide a tight threading which permits effective integration with the bone substance during the healing-in process and counteracts deformation or breaking-up of fine 35 bone trabeculae which surround the hole in the

2. Implant according to claim 1, characterized in that the implant threading is arranged to ensure

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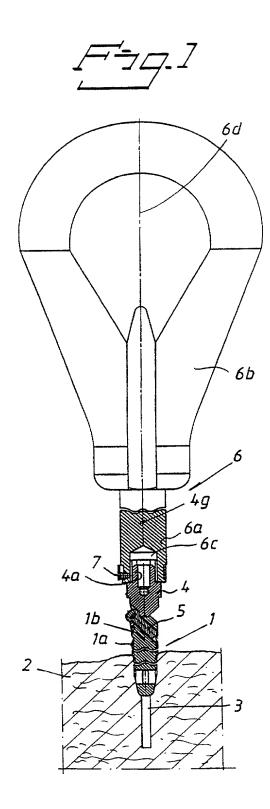
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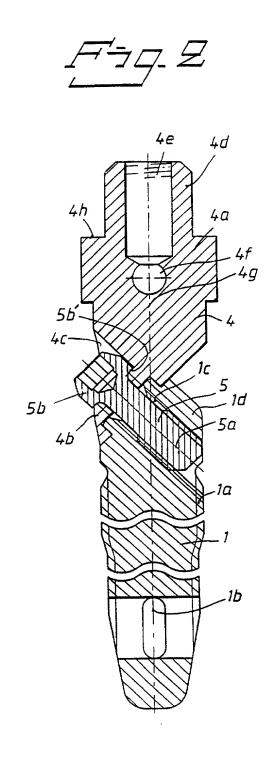
that the pressure (P, P') between the bone substance and the implant has essentially a constant or slightly increasing value during the greater part of the operation of screwing the implant into the hole.

- 3. Implant according to claim 1 or 2, characterized in that the front portion (tip) (3a) of the implant is designed with a conical thread (3e) which has a conicity essentially exceeding the conicity of the slightly conical thread (3d).
- 4. Implant according to claim 3, characterized in that the conicity of the slightly conical thread is chosen between 0.1 0.4 mm or has an angle of inclination (α) of about 0.5 2° , and/or the thread conicity of the thread at the said portion/tip (3a) is of the order of 0.4 0.8 mm or with an angle of inclination (β) of about 10 15° , and the portion/tip has a length or height (h) of about 10 30% of the length (L) of the threaded part of the implant.
- 5. Implant according to claim 1, characterized in that the implant threading along at least part of the longitudinal direction of the implant is given a noncircular or eccentric configuration (8a-8i) for the purpose of obtaining improved rotational stability of the implant in the recently inserted state or the incorporated state of the implant in soft/weak bone.
- 6. Implant according to claim 5, characterized in that the implant is arranged with a minimum diame35 ter (D') which corresponds to or is slightly greater, for example 1 5% greater, than the diameter (d) of the hole.

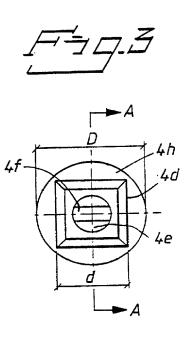
- 7. Implant according to claim 1 or any of claims 5-6, characterized in that the tip or the free end of the implant has a circular or concentric thread (3e) which merges gradually into a non-circular or eccentric thread on the remaining part or parts of the implant.
- 8. Implant according to claim 1 or any of claims 5-7, characterized in that the peripheris of the dif-10 ferent non-circular or eccentric thread cross-sections have bevelled corners (12) in order to avoid sharp corners.
- 9. Implant according to claim 1 or any of claims 5-8, characterized in that the non-circularity is arranged such that areas of maximum diameter are displaced in the peripheral direction from one thread turn (10) to the next thread turn (11).
- 20 10. Implant according to claim 1, characterized in that the number of thread spirals/thread entries is two, three or four.
- 11. Implant according to claim 10, characterized in that the number of thread spirals/thread entries is adapted to the number of cutting edges (5a, 5b, 5c, 5d) so that symmetrical cutting forces are obtained.
- 30 12. Implant according to claim 10 or 11, characterized in that two thread spirals are arranged on the implant together with two or four cutting edges, or in that three thread spirals are arranged together with three cutting edges, etc.

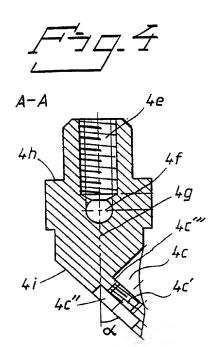
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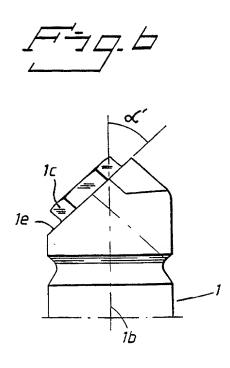


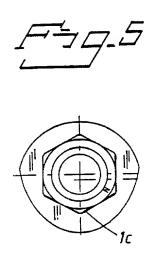


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DECLARATION FOR PATENT APPLICATION

Page Two

3	Full name of second joint inventor (if any), Fredrik Engman
Ì	Inventor's Signature Date May 22, 2000
0	Residence Address Häggvägen 19, S-435 37 Mölnlycke, SWEDEN SEX
:	Citizenship SWEDEN
	Post Office Address Same as residence
\leq	Full name of second joint inventor (if any): Roger_Fromell
	Inventor's Signature Ray Frank Date May 22, 2000
	Residence Address Malörtsvägen 11, 3-449 33 Nödinge, SWEDEN SEX
	Citizenship SWEDEN
	Post Office Address Same as residence
\supset	Full name of second joint inventor (if any): Lars Jörneus
fuc	Inventor's Signature Date May 22, 2000
. P. C.	Residence Address Riabergsvägen 7B, S-430 30 Frillesås, SWEDEN SEX
ur, den	Citizenship SWEDEN
12	Post Office Address Same as residence
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As a below-named inventor, I hereby declare that:

[XX] See next page for additional inventors

My residence, post office address and citizenship are as stated below next to my name

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

subject matter will		OR OBTAINING RELIABLE ANCHORI	NG OF A THREADED IMPLANT IN BONE	
the specification of	f which: (check one)			
is attached hereto.	[X] was filed on April 3, 2 amended on		tion PCT International Application Number PCT/SE98/	01982, and wa
I hereby state t referred to above.	that I have reviewed and underst	tand the contents of the above-identi	fied specification, including the claims, as amended by	any amendmen
Prior Foreign A	Application(s): I hereby claim to the listed below, or § 365(a) of an have also identified below any for	foreign priority benefits under 35 U y PCT international application whic	this application in accordance with 37 CFR § 1 56(a). S.C. § 119(a)-(d) or §365(b) of any foreign application a designated at least one country other than the United S.r's certificate having a filing date before that of the applications.	tates of Americ
priority is claimed	•			Priority Claime
SE970	4112-3	SWEDEN	November 11, 1997	[X] [
(Applica	ation No.)	(Country)	(Day/Month/Year Filed)	Yes N
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displacement of the second of			isted below and, insofar as the subject matter of each of	
	ttion Serial No.)	(Country)	d by 35 U.S.C § 112, first paragraph, I acknowledge the attention of the prior application and the national or PCT internation (Status-patented, pending, abandoned)	
initial proton.				
Townsend M. Bel No. 27,369, Elzbi Registration No	lser, Jr., Registration No. 22,956; leta Chlopecka, Registration No.	Morris Liss, Registration No. 24,510 32,767; Eric J. Franklin, Registration	Martin Abramson, Registration No. 24,852; Richard Wiener, Registration No. 25,787, George R F No. 37,134; Jeffri A. Kaminski, Reg. No. 42,709; and o prosecute this application and to transact all business	ettit, Registratı Wıllıam E. Cur
	Send Correspondence an	d Direct Telephone Calls to.	Elzbieta Chlopecka	
-	Elzbieta	Chlopecka	Pollock, Vande Sande & Amernick, R.L.L.P.	
	(202)		P.O. Box 19088	
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further that these	statements are made with the known	of my own knowledge are true and th owledge that willful false statements a	Washington, D.C. 20036–3425 U.S.A. at all statements made on information and belief are belief and the like so made are punishable by fine or imprisonme application or any patent issued thereon.	ved to be true, a
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